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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,819	03/18/2004	Rae Ellen Syverson	KCC 4749.1 (K-C 16,858.1)	7018
321	7590	11/30/2005	EXAMINER	
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			CHANNAVAJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/803,819		SYVERSON ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Lakshmi S. Channavajjala		1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 5, 12, 13 and 26-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11 and 14-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8-18-05</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Receipt of supplemental IDS dated 8-18-5 and remarks dated 9-13-05 is acknowledged.

Claims 1-60 are pending. Claims 1-4, 6-11 and 14-25 are drawn to elected invention and have been considered for examination. Claims 5, 12, 13 and 26-60 are withdrawn as being non-elected.

### ***Response to Arguments***

Applicant's arguments, filed 9-13-05, with respect to the rejection(s) of claim(s) 1-4, 6-11 and 14-25 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-4, 6-11 and 14-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,281,999 to Syverson et al (Syverson) in view of US 6,416,779 to D'Augustine et al (D'Augustine).

Syverson patent claims drawn to a method of inhibiting the production of TSST-1 from Gram-positive bacteria, comprising exposing the bacteria located in and around the vagina, to a vaginal cleansing formulation comprising thiomalonate, together with an effective amount of a second active agent. In particular, the second active agent of patented claim 3 has the same structural formula as that of the instant claims. Syverson teaches the composition for the same purpose i.e., inhibiting the production of TSST-1 from Gram-positive bacteria, as claimed in the instant. However, Syverson patent does not claim the specific non-absorbent substrates of the instant claims.

D'Augustine teaches a method for treating intravaginal or transvaginal bacterial, fungal, viral or parasitic infections comprising a device that contains a pharmaceutically effective amount of an antimicrobial, antifungal, antiviral or antiparasitic agent.

D'Augustine teaches the device in the form of a non-absorbent tampon or tampon-like device, intravaginal sponge or ring etc (col. 2, summary of invention, col. 3 & col. 7, lines 1-29, brief description of figure 15). D'Augustine fails to teach the claimed active agents of the instant invention. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use any non-absorbent article such as a tampon or sponge described by D'Augustine for applying the composition and in carrying out the patented method of Syverson because D'Augustine describes the

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intravaginal and transvaginal devices that can be successfully used for delivering antibacterial, antifungal antiprotozoal and other therapeutic agents to the vaginal mucosa and epithelium. A skilled artisan would have expected to administer the formulation of Syverson with the non-absorbent articles of D'Augustine for effective inhibition of the protein of *S. aureus*.

***Claim Rejections - 35 USC § 103***

Claims 1-4 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over a combination of US 4,470,9788 to Stolar and US 6,416,779 to D'Augustine or over US 5,728,690 to Chen and US 6,416,779 to D'Augustine in view of US 4,470,9788 to Stolar.

Stolar teaches a composition comprising trimethoprim, a sulfa drug and phenoxyethanol, for achieving a synergistic antibacterial effect (col. 1 and examples). Stolar however does not teach the non-absorbent articles of the instant claims.

D'Augustine teaches a method for treating intravaginal or transvaginal bacterial, fungal, viral or parasitic infections comprising a device that contains a pharmaceutically effective amount of an antimicrobial, antifungal, antiviral or antiparasitic agent.

D'Augustine teaches the device in the form of a non-absorbent tampon or tampon-like device, intravaginal sponge or ring etc (col. 2, summary of invention, col. 3 & col. 7, lines 1-29, brief description of figure 15).

Chen teaches a composition comprising hydrocortisone applied on applicators such as sponge or wipes, for topical applications. The composition of Chen further comprises phenoxyethanol (col. 3 and examples). Chen further teaches that the

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hydrocortisone compositions can be used as douche or toilette wipes (col. 1, lines 55-58).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add phenoxyethanol of Stolar phenoxyethanol to the non-absorbent feminine devices such as tampons, intravaginal sponge etc., described by D'Augustine for treating microbial or bacterial infections in the vaginal area of females because Stolar teaches phenoxyethanol as an effective antimicrobial agent and D'Augustine suggests effective delivery of antimicrobial or antibacterial compounds through the vaginal devices to vaginal mucosa and vaginal epithelium. Alternatively, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the composition of Chen comprising hydrocortisone together with phenoxyethanol on the vaginal devices such as douche (Chen), sponge, tampon etc (D'Augustine) because Stolar suggests that phenoxyethanol is an effective antimicrobial compound and accordingly a skilled artisan would have expected to effectively inhibit the bacterial infections by delivering the phenoxyethanol containing composition of Chen. Further, optimizing the amount of phenoxyethanol to be inserted on to the devices of D'Augustine.

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over a combination of US 4,470,9788 to Stolar and US 6,416,779 to D'Augustine or over US 5,728,690 to Chen and US 6,416,779 to D'Augustine in view of US 4,470,9788 to Stolar

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as applied to claims 1-4 and 6-10 above, and further in view of US 4,339,462 to Muntwyler et al (Muntwyler).

The references of Chen, Stolar and D'Augustine discussed above, fails to teach ethers as claimed in the instant invention.

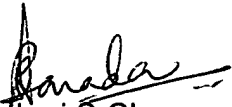
Muntwyler teaches antimicrobial compositions comprising hydroxydiphenyl ethers, as effective for combating microorganisms (col. 1-6) in various articles including personal products. Muntwyler particularly teaches that the ethers are effective against *Staphylococcus aureus*, the same species claimed in the instant. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the antimicrobial ether compounds of Muntwyler together with phenoxyethanol of Stolar or Chen and use them in the vaginal devices of D'Augustine because Muntwyler teaches that the compounds are effective against *S. aureus* and Stolar also teaches a combination of antimicrobial agents for synergistic effect. A skilled artisan would have expected to inhibit *S. aureus* more effectively by applying phenoxyethanol and ethers on the devices or articles of D' Augustine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
November 22, 2005